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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	4038.001	3234

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
08/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/831,272	KIRSCH ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/22/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8,9,22,39,42-47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,22,42,43 and 49* is/are allowed.

6)☒ Claim(s) *2,8,9,39 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to an amendment filed 5/22/09. Claims 2, 3, 8, 9, 22, 39, 42-47 and 49 are pending and under examination.

An Application Data Sheet has been filed with the amendment 5/22/09. The priority data in the ADS states, "This application is a continuation of U.S. Application No. 09/831,272 filed August 13, 2001, which is a §371 National Phase Application of PCT/EP99/08710, filed November 12, 1999". It is thus unclear whether the ADS should have been field with a subsequent case or if the ADS requires correction.

Applicants amendments to the Oath and the claims are sufficient to overcome the objections set forth in the action mailed 12/22/08.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8, 9, 39 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection or pathogen elicitor treatment and induction is between 10 and 15 fold wherein the promoter comprises 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7, consists of SEQ ID NO:11, comprises 4 copies of SEQ ID NO:11, comprises one copy or 4 copies of SEQ ID NO:11 followed respectively by one copy or 4 copies of SEQ ID NO:3 or 4 or 2) a chimeric promoter capable of mediating local gene expression in

plants upon pathogen infection and induction is between 15 and 81 fold wherein the promoter comprises either two copies of SEQ ID NO:11 or one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7 or 4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7 or two copies of SEQ ID NO:3 or 4 followed by two copies of SEQ ID NO:11 or two copies of SEQ ID NO:1 followed by two copies of SEQ ID NO:11, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This rejection is maintained for reasons of record in the office action mailed 5/22/09 and restated below based upon applicants amendment.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a chimeric promoter that is capable of directing elicitor-specific expression of a nucleic acid. The chimeric promoters are recited as inducing expression upon elicitor treatment of pathogen infection or pathogen elicitor treatment of 10-15 or greater than 10 fold. The specification teaches the identification of 7 elements that are capable of elicitor responsive expression alone or in combination with one another. The instant claims are

directed to chimeric promoters that are constructed using SEQ ID NO:11 or element D. The specification teaches that the following combinations with SEQ ID NO:11 have been tested and provide the fold induction mediated by these promoters of expression in plants. Induction is less than 10 fold when the elements are 4 copies of SEQ ID NO:3 or 4 followed by 4 copies of SEQ ID NO:11, induction is between 10 and 15 fold wherein the promoter comprises 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7, consists of SEQ ID NO:11, comprises 4 copies of SEQ ID NO:11, comprises one copy or 4 copies of SEQ ID NO:11 followed respectively by one copy or 4 copies of SEQ ID NO:3 or 4 or 2) a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection and induction is between 15 and 81 fold wherein the promoter comprises either two copies of SEQ ID NO:11 or one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7 or 4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7 or two copies of SEQ ID NO:3 or 4 followed by two copies of SEQ ID NO:11 or two copies of SEQ ID NO:1 followed by two copies of SEQ ID NO:11. Hence, it is clear that the combinations could not be predicted. Rather, the actual combination of elements to provide specific inductive levels does not really meet a pattern. For example 4 copies of SEQ ID NO:7 followed by 4 copies of SEQ ID NO:11 provide induction to 10 fold, however, 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7 provide induction up to 30 fold. The specification states that the difference in levels is due to steric hindrance (see page 37). Further confusing the issue is that two copies of SEQ ID NO:7 followed by 2 copies of SEQ ID NO:11 induce to 81 fold. Hence, the patterns of induction are not predictable and must be empirically determined. As well, the recitation of greater then 15 fold has no upper limit whereas the results suggest that in fact there is an upper limit.

This exacerbates the unpredictability of determining which embodiments are productive as the claims broadly recite components of the promoter. For example, claim 2 recites that expression is between 10-15 fold whereas the promoter comprises two or more cis-acting elements wherein at least one of the elements consists of SEQ ID NO:11. A promoter comprising one copy of SEQ ID NO:11 can have innumerable elements associated with only a fraction of which have been tested. However, when looking to the assessed combinations, it is clear that not all have inductive levels of 10-15 fold and furthermore, considering all the combinations that are possible aside from the disclosed combinations provides a large genus of promoters wherein the ability to predict function is uncertain.

Given the lack of guidance in the specification, the large and diverse group of chimeric promoters recited and the highly unpredictable nature of the ability to predict components to produce a promoter with specific induction levels, it is concluded that a person of skill in the art would have had to conduct undue experimentation in order to practice the claimed

Response to Amendment

Applicants argue that they broadly teach cis-elements that are capable of inducing high-level expression of operably l inked sequences. However, the claimed invention is not commensurate in scope with the claims. In essence, each of applicants combined cis elements is a unique species in that the functionality is unique. The species provided does not entail a pattern from which one could predict the functionality of related element combinations. In particular the evidence of record is not clear as to why different arrangements give the expression levels they do. There does not appear to be a predictability in simply increasing the

number of promoters. For example a promoter comprising at least one element comprising SEQ IDNO:11 encompasses a number of elements that provide greater than or less than 15 and 10 respectively. Hence, one could not predict from the numerous possibilities of promoters that comprise SEQ ID NO:11 which would met the claim limitations. The specification is not commensurate in scope with the claimed invention as it only details a fraction of those promoters comprising SEQ ID NO:11 that are between 10 and 15. An element comprising 2 SEQ ID NO:11s is greater than 15 fold and an element comprising 4 of SEQ IO NO:11 following 4 of SEQ ID NO3 is less than 10 fold.

The unpredictability of predicting the activity of combinations of promoter elements is exacerbated by the recitation in the amendment that the induction is over activation if any by abiotic stress. The recitation is not new matter as the specification teaches "Preferably, the induction from the chimeric promoter upon pathogen attack or elicitor treatment is at least about l O-fold higher, preferably 20-fold higher and particularly 30-fold higher than its activation, if any, by abiotic stress (page 3). However, one could not predict at activation level of any of the claimed or disclosed promoters over abiotic stress activation as the specification does not disclose how to determine this or what the known levels over abiotic stress are. The specification teaches,

> 4. Transient transfection and expression assays
>
> The transient transfection and expression assays were essentially carried out as described in Dangl, EMBO J. 6 (1987), 2551-2556; Schulze-Lefert, EMBO J. 8 (1989), 651-656; van de L6cht, EMBO J. 9 (1990), 2945-2950. Briefly, five day old subcultured parsley cells are used for the isolation of protoplasts. Protoplasting is achieved by overnight incubation of the cells in 0.24 M CaCI2 containing 0.25% (w/v) cellulase and 0.05% (w/v) macerozyme at 24° C. Protoplasts are collected by centrifugation (7 min., 100 g), washed with 0.24 M CaCI2, and then floated in B5 medium (GIBCO/BRL) containing

> 0.4 M sucrose and 1 mg/ml 2,4- dichlorophenoxyacetic acid. Protoplasts floating after centrifugation (5 min, 100 g) were harvested, counted and adjusted to 2 x 106/ml.
>
> Supercoiled or linearized plasmid DNA (5 -20/Jg) containing the chimeric promoter-reporter(GUS) construct was transferred into the protoplasts using the polyethylene glycol (PEG) method (Krens, Nature 296 (1982), 72-74). Each transformation assay was split and placed into two 3 ml plates. The Pep25 (NQrnberger, Cell 78 (1994), 449-460) elicitor was added to one whereas the other served as a control. Both samples were harvested after 8 hours, frozen in liquid nitrogen, crude protein extracts prepared and GUS activity assayed (Jefferson, Plant Mol. Biol. Rep. 5 (1987), 387-405). Bradford assays (Bio-Rad) were used for protein determination. The expression data are given as mean fold induction values +_ standard deviation (SD) and mean GUS activity (pmol/min/mg) from six independent transient transfection assays treated with or without Pep25 elicitors

The methods detail use of "a control" which is a broad term. One cannot from the specification make or use the broad breadth of the recited claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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